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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/841,836 | 04/25/2001 | Bruce L. Roberts | GA0229 | 5822 |

24536 7590 06/01/2006

GENZYME CORPORATION
LEGAL DEPARTMENT
15 PLEASANT ST CONNECTOR
FRAMINGHAM, MA 01701-9322

| EXAMINER | |
|---|---|
| CHEN, STACY BROWN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1648 | |

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/841,836 | ROBERTS ET AL. | |
| | Examiner | Art Unit | |
| | Stacy B. Chen | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *2-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's Appeal Brief filed March 20, 2006 is acknowledged. Upon further consideration of the claimed subject matter, prosecution in this application is reopened in order to make the following rejection. The finality of the Office action of February 23, 2005 is withdrawn. Any inconvenience to Applicant is regretted.

2. Claims 1-20 are pending. Claims 1-6 are under examination. Claims 7-20 remain withdrawn from consideration being drawn to non-elected inventions.

### *Response to Arguments*

3. The rejection of claims 1, 5 and 6 under 35 U.S.C. 102(e) as anticipated by Blaschuk *et al.* (US Patent 6,358,920, herein, "Blaschuk") is withdrawn in view of Applicant's persuasive arguments. For the same reason, the rejection of claims 2-4 under 35 U.S.C. 103(a) as obvious over Mounts *et al.* (WO 98/52615) in view of Blaschuk and Lisziewicz *et al.* (US Patent 6,420,176) is withdrawn.

Previously, the examiner asserted that Blaschuk teaches that polynucleotides may function as modulating agents (col. 68, lines 10-11). Blaschuk teaches that polynucleotides may be incorporated into a viral vector (col. 68). Also taught is that modulating agents may be linked to a support molecule or a solid support (col. 15, lines 5-7). The examiner reasoned that polynucleotides incorporated into vectors would still be considered modulating agents, and whatever uses described for the modulating agent as a polynucleotide would convey to the modulating agent as a vector. One would recognize from Blaschuk's teachings that the

polynucleotides or vectors containing them may be linked to a support molecule or solid support, such as a bead or other support listed in col. 68. The examiner concluded that Blaschuk contemplates vectors comprising the subject polynucleotides attached to a support molecule. This understanding of the Blaschuk reference was reflected in the 103 rejection as well.

In the Appeal Brief filed March 20, 2006, Applicant primarily argues the following: Applicant acknowledges that Blaschuk does teach adenovirus particles as a means for polynucleotide delivery. Applicant also acknowledges that Blaschuk teaches a micro-platform material as a linker for modulating agents. Applicant argues that Blaschuk does not teach that adenoviral vectors may be targeted for delivery using microspheres/beads. Applicant asserts that Blaschuk teaches two independent modes of delivery of the polynucleotides: viral vectors and microsphere/beads, but not in combination. Applicant argues that in view of the deficiencies of Blaschuk, the rejection under 35 U.S.C. 102(e) and 103(a) should be withdrawn.

In response to Applicant's arguments, the rejections are withdrawn in view of Applicant's persuasive arguments and the teachings of Blaschuk.

***Claim Rejections - 35 USC § 102***

4. (*New Rejection*) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Beer *et al.* (*Advanced Drug Delivery Reviews*, 1997, 27:59-66, "Beer"). Claim 1 is drawn to an adenovirus particulate

comprising a plurality of adenovirus particles complexed to an insoluble micro-platform material. The particles are individual adenovirus virions. The micro-platform material refers to a solid, insoluble substance. It comprises a particle of suitable dimensions so that it may be engulfed by a phagocytic cell, such as a dendritic cell.

Beer teaches recombinant adenoviral vectors carrying foreign genes in biodegradable poly (lactic-glycolic) acid (PLGA) microspheres (abstract). This form of polymer encapsulation delivers drugs at controlled rates (page 60, second column, third full paragraph). The encapsulation process involves the formation of double emulsions consisting of oil-water layers. The viruses are mixed with the polymer (PLGA) in an organic solution in the presence of an emulsifier. The end product is an aqueous layer containing virus, surrounded by a PLGA polymer layer (page 61, Figure 1). The microspheres containing the viruses are expected to be capable of being engulfed by phagocytic cells.

The definition of "insoluble micro-platform material" refers to a solid, insoluble substance. This definition is relative and does not confer any distinguishing feature to the micro-platform material, as nearly any material may be dissolved using the appropriate solvent, including fibers and microbeads (see claim 5). Thus, the PLGA polymer that encapsidates (complexes with) the adenoviral vector meets the limitation of claim 1, with regard to the insoluble micro-platform material. Therefore, claim 1 is anticipated by Beer's teachings.

***Conclusion***

5. Claim 1 is rejected. Claims 2-6 are objected to solely for depending from a rejected claim. The subject matter of claims 2-6 is free of the prior art of record.

The following references made of record but not relied upon are considered pertinent to Applicant's disclosure, though not prior art. Pandori *et al.* (*Virology*, **2002**, 299:204-212) teaches adenovirus-microbead conjugates for gene delivery (abstract). Pannier *et al.* (*Molecular Therapy*, **2004**, 8 pages) is a review of controlled release systems for DNA delivery. Also discussed is the delivery of viruses and viral vectors using polymeric delivery, such as encapsulation and chemical modification (page 5).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Stacy B. Chen 5/30/06

Stacy B. Chen
Primary Examiner
May 30, 2006